

# EXHIBIT D

# Richard Ellerkmann

## General Reliance List *in Addition to Materials Referenced in Report*



## Richard Ellerkmann Materials List

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Zhu L, et al. [Pop 21, 18-60 mos, median 43.5 mo fu] Modified laparoscopic sacrocolpopexy with mesh for severe pelvic organ prolapse. Int J Gynecol Obstet 121 (2013) 170-172.
Zyczynski HM, et al. (Prosima Study investigators) One-year clinical outcomes after prolapse surgery with nonanchored mesh and vaginal support device. Am J Obstet Gynecol 2010; 203: 587.e1-8.



## Richard Ellerkmann Materials List

## Production Materials

Document Description [Bates Range]
000001_4275674_d_Use of Gynemesh PS in Prolapse Surgery Power Point
2001 TVT Surgeon's Monograph
2003 Gynemesh PS Early Clinical Experience White Paper
2003 Gynemesh PS white paper. Gynemesh PS Early Clinical Experience.
2004 Gynemesh PS Study Poster - AUGS 2004 San Diego. Lucente V, Hale D, Miller D, Madigan J. A Clinical Assessment of Gynemesh PS for the Repair of Pelvic Organ Prolapse.
2007 Prolift Prof Ed Slides
Clinical Evaluation Report - Gynemesh PS by Piet Hinoul - April 26, 2013
ETH.MESH.00012009-089 - TVM Prospective Data (French Trial) - Exhibit 522
ETH.MESH.00013529-534 - Prolift+M IFU
ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP – Pelvic Floor Surgery and Anatomic Dissection Lab
ETH.MESH.00167104 - 2006 TVT Laser Cut Clinical Expert Report
ETH.MESH.00295355 (TVTE-338-10-7.12) - 2010 TVT-Exact Prof Ed
ETH.MESH.00308094 (2629_2006-07-12) - 2006 TVT-Secur
ETH.MESH.00354732 (TVTA-088-11-2.13) - 2011 TVT-Abbrevio
ETH.MESH.00369995 (2008-570) - 2008 TVT Family of Products Prof Ed
ETH.MESH.00369999 (2008-135) - 2008 TVT-Secur
ETH.MESH.00370421 (TVTO_0113-09-8.11) - TVT-O FDA Public Health Notice
ETH.MESH.00373310 (2003-712) - 2003 TVT Prof Ed
ETH.MESH.00393045-46 (2008-582) TVT-O Procedural Steps
ETH.MESH.00394849 - Gynemesh PS Panel Powerpoint - Drs. Robinson, Miller, Winkler, England
ETH.MESH.00395374-380 - 2001 June 22; Scientific Advisory Chicago Meeting re POP mesh includes Prolene Soft
ETH.MESH.00397674 (2002-275) - 2002 Minimizing & Managing TVT Complications Prof Ed
ETH.MESH.00520649-722 - 2006 US TVM 12 Month Clinical Report
ETH.MESH.00523617 (2007-4144) - 2007 TVT-Secur Critical Steps
ETH.MESH.00523942 (2005-1638) Waltregny TVT-O Summit
ETH.MESH.00637343 - 2004 ETHICON Product Development Process - Gynemesh PS
ETH.MESH.00747864-874 - Gynemesh PS DDSA Rev.
ETH.MESH.00747864-874 - Gynemesh PS DDSA Rev. 2
ETH.MESH.00993273 (2091_2006-02-01) - 2006 TVT-O Summit Presentation by Raders and Lucente
ETH.MESH.01128679-98 (TVTS007) - 2007 TVT-Secur Procedural Steps
ETH.MESH.01222075 - 2006 Kammerer Memo
ETH.MESH.01261962 (2005-1819) - TVT-O Summit by Raders, Rogers, Lucente
ETH.MESH.02219584 - 2010 Scion PA Unmet Needs Exploratory Research
ETH.MESH.02330776 (TVTO-384-10-8.12) - TVT-O
ETH.MESH.02341398-410 - Prosima IFU
ETH.MESH.02341454-459 - Prolift 2007-2009 IFU
ETH.MESH.02341522-527 - Prolift 2005-2007 IFU
ETH.MESH.02341658-664 - Prolift 2010-2012 IFU - Text Searchable
ETH.MESH.02341734-740 - Prolift 2009-2010 IFU
ETH.MESH.02342097 Prolene Soft IFU
ETH.MESH.02342101 Prolene Soft IFU



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## Production Materials

ETH.MESH.02342102 Prolene Mesh IFU
ETH.MESH.02342152-54 Prolene Mesh IFU
ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh
ETH.MESH.02616825-27 Prolene Soft IFU
ETH.MESH.03458123-38 - TVT Patient Brochure 3.19.08
ETH.MESH.03460813-853 - Prolift Surgeons Resource Monograph 2007
ETH.MESH.0370392 (3914_2007-08-22) - 2007 TVT-Secur
ETH.MESH.03715787-793 - Gynemesh PS CER (2002) - Weisberg
ETH.MESH.03751819 (2009-473) - 2009 The Science of What's Left Behind
ETH.MESH.03905968-975 - Prolift 2005 Brochure
ETH.MESH.03905976-991 - Prolift 2006 Brochure
ETH.MESH.03906001-020 - Prosima and Prolift+M
ETH.MESH.03906037-052 - Prolift 2008 Brochure
ETH.MESH.04046302 (TVT and TVT-O)(2005-1117)
ETH.MESH.04079609 (TVTA-401-10-8.12) - 2010 TVT-Abbrevio
ETH.MESH.04202101 (2008-448)
ETH.MESH.05222686-88 - TVT IFU (4th version) 4.7.06-10.7.08
ETH.MESH.05320909 (2008-135)(38 slides summit) - 2008 TVT-Secur
ETH.MESH.05795421 (2001-227) - 2001 TVT Prof Ed
ETH.MESH.05795537 (1998-218) - 1998 TVT Prof Ed
ETH.MESH.07201006 - Prolift Prof Ed 2007 Slide Deck
ETH.MESH.07246690-19 - Study Report - A systematic review of patient-years of experience in prospective randomized controlled trials (RCTs) in incontinence.
ETH.MESH.08003279-94 - TVT Patient Brochure 12.10.08
ETH.MESH.08117473 - 2012 TVT-Exact Updated Prof Ed Slide Deck w Production Cover
ETH.MESH.08156958 (2002-310) - 2002 TVT Advanced Users Forum Presentation
ETH.MESH.08307644-45 - 4.05.2013 - Email from P. Hinoul to G. Callen re: RCT data (with attachments).
ETH.MESH.09100506 - Prolift Prof Ed 2005 Slide Deck
ETH.MESH.09744840-45 - TVT Patient Brochure 2.14.13
ETH.MESH.10027307-28 - Surgeon's Resource Monograph
ETH.MESH.10686760-771 - Gynemesh PS aFMEA 2013
ETH.MESH.10686833-852 - Risk Management Report (RMR) for Gynemesh PS 2013
ETH.MESH.11543641 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
ETH.MESH.11543719 - Robinson Gynemesh PS Presentation Awareness Module 4.7.04
ETH.MESH.22625140-45 - MDD CAPA # CAPA-003474
ETH.MESH.22631022-29 - Response to Section 39 Request, D-1, 1-1002
Gynecare Gynemesh PS IFU (English Only) LAB-0012266 Rev: 3, released 02.03.15.
Gynecare TVT IFU changes redlined, D-6, 1-20
Gynemesh PS 510k Approval File [FDA]
Gynemesh PS white paper - Early Clinical Experience



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**Production Materials**

K013718 GYNEMESH PS (Ethicon) Corrected SE Letter (07-Nov-2012)
May 2010 CER for Gynemesh PS signed by David Robinson
PS120046 A2 - 7.9.12 FDA Response to Ethicon re Gynemesh PS
TVT IFU (7th version) 2015 - Present - from Ethicon website.
TVT, TVT-O, and Gynemesh PS/ Prolift IFUs, Surgeons' Monographs, Professional Education Slides



**Richard Ellerkmann Materials List**

**Company Witness Depositions**

Hinoul, Piet - 01.15.2014 Deposition Testimony
Weisberg, Martin - 11.13.2015 Deposition Testimony



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## Other Materials

2011 IUGA Patient Brochure - Vaginal Repair with Mesh Patient Brochure
2008 FDA Public Health Notification: Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence.
2012 ABOG and ABU Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery
2012 ABOG Guide to Learning in Female Pelvic Medicine and Reconstructive Surgery
2012 AUA Guidelines - Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update - Appendices A11 and A16
2013 AUA Position Statement on the Use of Vaginal Mesh for the Surgical Treatment of Stress Urinary Incontinence.
2013 AUGS Guidelines for Privileging and Credentialing Physicians for Sacrocolpopexy for Pelvic Organ Prolapse
2013 FDA Statement regarding Considerations about Surgical Mesh for SUI
2014 IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence
2015 ACOG Practice Bulletin #155 Summary - Urinary Incontinence in Women, 1120-1122
2016 AUGS, SUFU, ACOG, SGS, AAGL, NAFC, WHF, Position Statement - Mesh Midurethral Slings for Stress Urinary Incontinence
2016 IUGA Patient Brochure on Midurethral Sling Procedures for Stress Incontinence
2017 ACOG, AUGS - Committee Opinion on Complications in Gynecologic Surgery, 1-6, Management of Mesh and Graft Complications in Gynecologic Surgery.
2017 AUA, SUFU Guideline - Surgical Treatment of Female Stress Urinary Incontinence, 1-33
2018 AUGS, SUFU, AAGL, ACOG, NAFC, SGS, Position Statement - Mesh Midurethral Slings for Stress Urinary Incontinence
2018 RANZCOG Position Statement on SUI and POP
ACGME Program Requirements for Graduate Medical Education in Female Pelvic Medicine and Reconstructive Surgery
ACOG Committee Opinion, Gynecologic Surgery in the Obese Women. No. 619, January 2015.
AUGS Residency Guidelines
AUGS Resident Learning Objectives
Code of Federal Regulations Title 21, as of 4/1/15. 21CFR801.109
Up To Date